AAPS Workshop on Streamlining the CMC Regulatory Process for NDAs and ANDAs

Co-Sponsored with FDA

June 11-13, 2001 • Hyatt Regency Washington On Capitol Hill • Washington, DC

aaps American Association of Pharmaceutical Scientists

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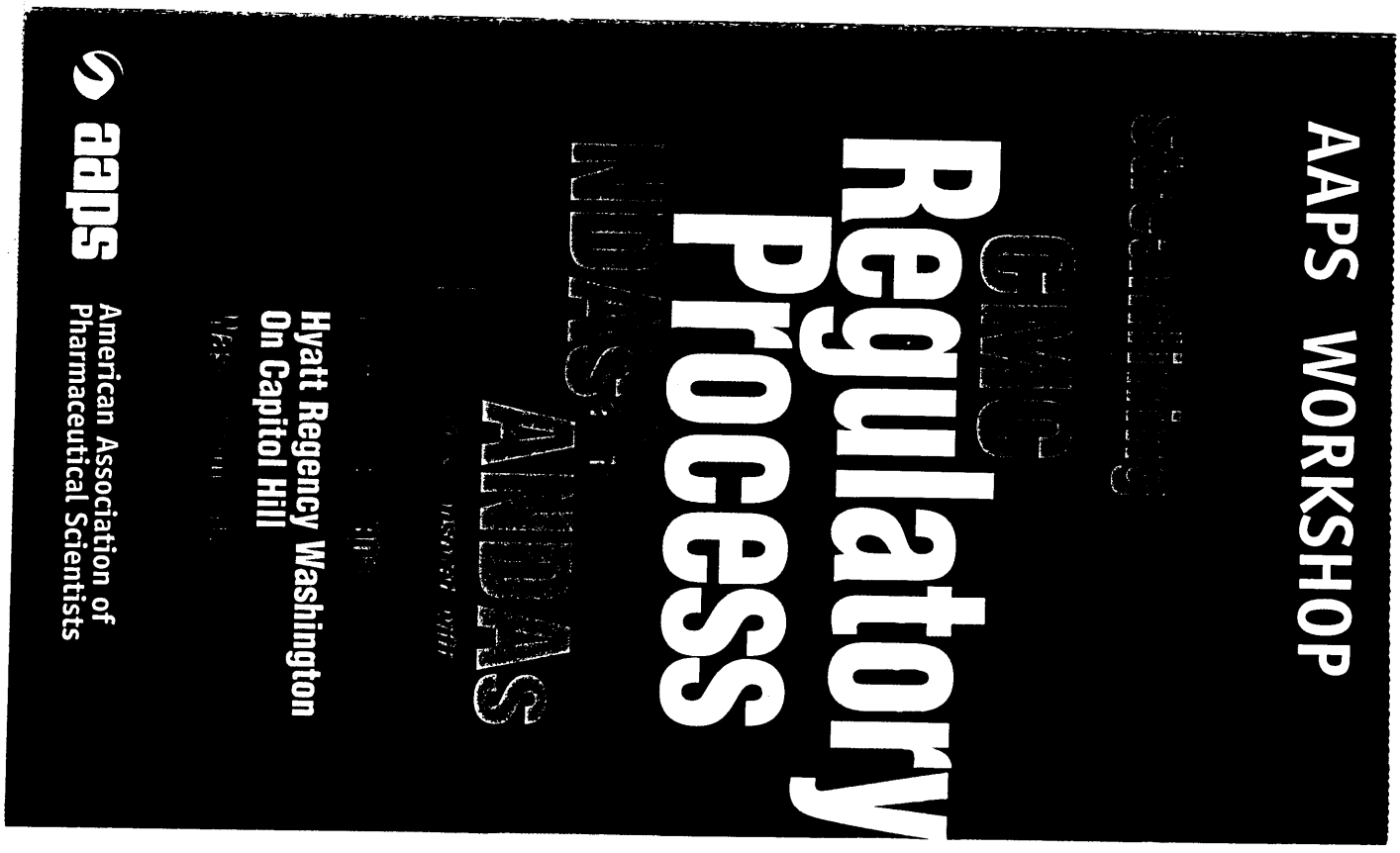
Register by April 27 and Save!!



D

Review the FDA categorization of post-approval changes as major, moderate or minor as reflected in the November 1999 guidance on ***Changes to An Approved NDA or ANDA***.

Discuss industry experience in and perspective on using the guidance.

Identify parts of the guidance that may warrant revision.

Provide a forum to discuss a new initiative under investigation by FDA which, for specific drugs, will:

- Reduce the CMC information and data to be included in original ANDAs
- Eliminate many NDA/ANDA manufacturing supplements
- Reduce the CMC information and data included in NDA/ANDA manufacturing supplements

Develop scientific, risk-based criteria that could be used to identify drug substances and products that would be eligible for the new initiative.

Prepare a summary report that can be considered by FDA when revising the guidance on ***Changes to an Approved NDA or ANDA*** and in developing the guidance for the new initiative.

Planning Committee

Preliminary Program

Sunday, June 10

5:00 pm – 7:00 pm
REGISTRATION

Monday, June 11

7:00 am – 5:15 pm
REGISTRATION

8:00 am – 12:00 pm
Changes to an Approved NDA or ANDA
Moderators
Yuan-yuan Chiu, Ph.D.
Tobias Massa, Ph.D.

8:00 am – 8:20 am
Welcoming Remarks
Yuan-yuan Chiu, Ph.D.
Food and Drug Administration
Tobias Massa, Ph.D.
Eli Lilly and Company

8:20 am – 8:40 am
Background/History
Nancy Sager
Food and Drug Administration

8:40 am – 9:05 am
Components and Composition/ Manufacturing Site Changes
Rashmikant Patel, Ph.D.
Food and Drug Administration

9:05 am – 9:35 am
Manufacturing Process Changes
Frank Holcombe, Ph.D.
Food and Drug Administration

9:35 am – 10:00 am
Tests and Acceptance Criteria Changes
John Simmons, Ph.D.
Food and Drug Administration

Acronym Key

ANDA Abbreviated New Drug Applications
CMC Chemistry and Manufacturing Controls
FDA Food and Drug Administration
NDA New Drug Application

Monday, June 11 *(Continued)*

10:00 am – 10:30 am
BREAK

10:30 am – 10:50 am
Labeling, Miscellaneous and Multiple Changes
Florence Fang
Food and Drug Administration

10:50 am – 11:20 am
Sterile Drug Substances/Drug Product Changes
Peter Cooney, Ph.D.
Food and Drug Administration

11:20 am – 11:40 am
PhRMA Industry Perspective
David Miner, Ph.D.
Eli Lilly and Company

11:40 am – 12:00 pm
Generic Industry Perspective
Christine A. Mundkur
Barr Laboratories, Inc.

12:00 pm – 1:00 pm
LUNCH *(Complimentary to all registrants)*

1:00 pm – 2:15 pm
CONCURRENT BREAKOUT SESSIONS
(Please select one)

- **A: Sterile Drug Substances/Drug Products**
- **B: Manufacturing Process**
- **C: Components and Composition/ Manufacturing Site**
- **D: Tests and Acceptance Criteria**
- **E: Labeling, Miscellaneous and Multiple**

2:25 pm – 3:40 pm
CONCURRENT BREAKOUT SESSIONS
Repeated

3:40 pm – 4:00 pm
BREAK

4:00 pm – 5:15 pm
CONCURRENT BREAKOUT SESSIONS
Repeated

5:15 pm – 6:15 pm
RECEPTION

Preliminary Program

Tuesday, June 12

7:30 am – 4:30 pm
REGISTRATION

8:00 am – 10:10 am
Risk-Based CMC Review
Moderator
Tobias Massa, Ph.D.

8:00 am – 8:10 am
Reconvening Opening Remarks
Tobias Massa, Ph.D.
Eli Lilly and Company

8:10 am – 8:30 am
A New Initiative
Yuan-yuan Chiu, Ph.D.
Food and Drug Administration

8:30 am – 8:50 am
Drug Substance Criteria
Eric Duffy, Ph.D.
Food and Drug Administration

8:50 am – 9:10 am
Drug Product Criteria
Vilayat Sayeed, Ph.D.
Food and Drug Administration

9:10 am – 9:20 am
Microbiological Criteria
Peter Cooney, Ph.D.
Food and Drug Administration

9:20 am – 9:30 am
cGMP Criteria
Patricia Alcock
Food and Drug Administration

9:30 am – 9:50 am
Generic Industry Perspective
Nicolas Maselli
Zenith Goldline Pharmaceuticals

9:50 am – 10:10 am
PhRMA Industry Perspective
Richard P. Poska, R.Ph.
Abbott Laboratories, Inc.

10:10 am – 10:40 am
BREAK

10:40 am – 12:00 pm
CONCURRENT BREAKOUT SESSIONS
(Please select one)

A: Drug Substance

B: Drug Product

C: Microbiology

D: GMPs

Tuesday, June 12 *(Continued)*

12:00 pm – 1:00 pm
LUNCH *(Complimentary to all registrants)*

1:00 pm – 2:30 pm
CONCURRENT BREAKOUT SESSIONS
Repeated

2:30 pm – 3:00 pm
BREAK

3:00 pm – 4:30 pm
CONCURRENT BREAKOUT SESSIONS
Repeated

Wednesday, June 13

7:30 am – 11:45 am
REGISTRATION

8:00 am – 11:20 am
Summary and Conclusions
Moderator
Yuan-yuan Chiu, Ph.D.

8:00 am – 8:10 am
Reconvening Opening Remarks
Yuan-yuan Chiu, Ph.D.
Food and Drug Administration

8:10 am – 9:10 am
Monday Breakout Session Summaries

9:10 am – 9:30 am
Panel Discussion
Monday Speakers

9:30 am – 10:00 am
BREAK

10:00 am – 11:00 am
Tuesday Breakout Session Summaries

11:00 am – 11:20 am
Panel Discussion
Tuesday Speakers

11:20 am – 11:45 am
Overall Summary, Conclusions and Next Steps
Yuan-yuan Chiu, Ph.D.
Food and Drug Administration
Tobias Massa, Ph.D.
Eli Lilly and Company

Visit
www.aapspharmaceutica.com/cmc
to register
breakout session information

Meeting Information

Workshop Fees

Save by registering early.

	On or Before 04-27-01	After 04-27-01
AAPS Member	$670	$775
Non-Member	$1005	$1165
AAPS Member (Government)	$175	$225
Non-Member (Government)	$175	$225
AAPS Student Member	$55	$85
Continuing Education	$30	$30

Payment of fees is required with registration.

Cancellation Policy

All refund requests must be in writing. Refunds will be issued less an administrative fee ($170 for registrants, $50 government registrants/$15 student registrants). Registrant substitutions from the same company may be submitted in writing at any time without penalty. If the membership status of the substitute differs from that of the original registrant, a refund or additional charge may apply. All refunds will be issued after the meeting has occurred. **No refunds will be issued for requests received after May 14, 2001.**
Submit cancellation requests in writing to:
Fax: 703-243-5682
E-mail: registration@aaps.org
Deadline: May 14, 2001

Continuing Education

Continuing education credits are provided by the University of Wisconsin, an approved provider of continuing pharmaceutical education.
Earn 1.2 CEUs (12 credit hours).
Program number: 073-999-01-038-L04
Fee: $30 payable with registration.
The fee must be paid at the time of registration or on site. Continuing education credit will not be available after the meeting has occurred.

Hotel Accommodations

Discounted AAPS rates!

Hyatt Regency Washington On Capitol Hill
400 New Jersey Avenue, NW
Washington, DC 20001
Call: 202-737-1234
Fax: 202-942-1578

Room Rates: single: $189; double: $214; triple: $239; or quad: $264 per day + tax (currently 14.5%)
Parking: $24 per day
Deadline: May 14, 2001

You may use the form in this brochure to reserve your room. If you call in your reservations, tell them you are participating in this workshop to receive the AAPS rates. Reservations made after the deadline can only be honored if space and rates are available.

Directions: From Ronald Reagan National Airport, the hotel is 15 minutes by taxi or complimentary hotel shuttle.

Metrorail stops two blocks from the hotel. (Red Line "Union Station") Exit the front of Union Station towards Massachusetts Avenue. Cross Massachusetts Avenue and turn right on E Street. Turn left at New Jersey Avenue and the hotel is on your right.

Special Airfares

Special airfares have been negotiated with airlines for workshop attendees flying to/from Washington, DC. To take advantage of these discounts please call the official AAPS travel agency Navigant International at 1-800-669-6024 and mention this workshop. You may also call the airlines directly. Certain restrictions may apply and seats are limited. Times are listed as Eastern Standard Time (EST).

Delta Airlines
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Mon-Fri 7:30 am – 11:00 pm EST
Sat or Sun 8:30 am – 11:00 pm EST
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8:00 am – 9:30 pm EST
Gold File Number: 77681493